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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/876,091	06/08/2001	Klaus-Ulrich Weithmann	02481.1748	9372

22852 7590 04/17/2002

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EXAMINER

GITOMER, RALPH J

ART UNIT

PAPER NUMBER

1627

DATE MAILED: 04/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/876,091

Applicant(s)  
Weithmann

Examiner  
Ralph Gitomer

Art Unit  
1627



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Feb 4, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-17 is/are pending in the application.
- 4a) Of the above, claim(s) 4-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s): \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5 20) ☐ Other: \_\_\_\_\_

The preliminary amendment received 7/9/2001 is now entered and claims 1, 3-17 are currently pending in this application. It is noted no foreign search report has been submitted.

On page 5 first full paragraph of the specification, it would appear the point of novelty of the invention regards the marker substrate may inhibit the enzyme but the inhibition by the marker substrate did not occur with incubation of only the catalytic domain of collagenase with the substrate collagen II and the marker substrate to some degree. Please explain how only the catalytic domain can be incubated. It is understood that there is a difference between the binding site and catalytic site and it would appear there may be an intention of distinguishing an effect of an inhibitor on only the catalytic domain, not the binding. And note this feature is not claimed. The enzyme, the substrate, the marker substrate are all old and the inhibition by the marker substrate upon the activity of the enzyme is also old.

Applicant's election with traverse of Group I in Paper No. 7 is acknowledged. The traversal is on the ground(s) that it would not be a serious burden to search all the groups. This is not found persuasive because The inventions are separate and distinct.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1 and 3 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly  
5 connected, to make and/or use the invention.

The claims are directed to determining if a substance is an inhibitor or a ligand and Table 1 is presented on page 11 of the specification. However, no specific compounds and the data obtained is shown to be correlated to the compounds being  
10 inhibitors only.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a single substrate-collagen, a single enzyme-collagenase, and a single  
15 marker substrate, does not reasonably provide enablement for an protein, any marker and any substrate. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

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The entire scope of the claims has not been enabled because:

1. Quantity of experimentation necessary would be undue because of the large proportion of inoperative compounds claimed.
  2. Amount of direction or guidance presented is insufficient to predict which substances encompassed by the claims would work.
  3. Presence of working examples are only for specific substances and extension to other compounds has not been specifically taught or suggested.
  4. The nature of the invention is complex and unpredictable.
  5. State of the prior art indicates that most related substances are not effective for the claimed functions.
  6. Level of predictability of the art is very unpredictable.
  7. Breadth of the claims encompasses an innumerable number of compounds.
  8. The level of one of ordinary skill in this art is variable.
- In re Wands, 858 F.2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)

Claims 1 and 3 rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

In claim 1(c) ~~can bind~~ does not state what actually occurs. Claim 1 is directed to determining whether a test substance is an inhibitor or a ligand but lacks any correlating step to determine that. In claim 3, how the protein is used is not set forth. Note that use is not a statutory invention.

The title of the invention is not aptly descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following prior art pertinent to applicant's disclosure is made of record and not relied upon:

Weithmann (Inflammation Research) teaches the presently claimed marker substrate for determining inhibition of the same enzymes without the substrate present.

Fields (5,770,691) teaches determining MMP's.

Kolkenbrock (Biol Chem) teaches determining MMP's.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (703) 308-0732. The examiner can normally be reached on Tuesday-Friday from 8:00 am - 5:00 pm. The examiner can also be reached on alternate Mondays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat can be reached on (703)

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308-2439. The fax phone number for this Art Unit is (703) 308-4556. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235. For 24 hour access to patent application information 7 days per week, or for filing applications electronically, please visit our website at [www.uspto.gov](http://www.uspto.gov) and click on the button Patent Electronic Business Center for more information.



Ralph Gitomer  
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